WHEREAS this action may involve the discovery and disclosure of certain information, documents and things in the possession, custody or control of the plaintiffs, Genentech, Inc. and Roche Palo Alto LLC (collectively, "Roche"), the defendant, Sandoz Inc. ("Sandoz"), or non-parties, that

parties subject to pleading, discovery or disclosure in this action be treated as confidential;

constitute or contain trade secrets or other confidential research, development or commercial information within the meaning of Rule 26(c) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.");

WHEREAS, the parties have stipulated that certain information, documents and things of the

WHEREAS such confidential information must be protected in order to preserve the legitimate business interests of the parties or non-parties; and

WHEREAS the parties, through counsel, stipulate that good cause exists for the entry of this Protective Order pursuant to Rule 26(c) for the purpose of advancing the progress of this case and to prevent unnecessary dissemination or disclosure of such confidential information.

Accordingly, by the United States District Court for the Northern District of California, it is ORDERED:

DEFINITIONS

- 1. The term "Protected Information" shall mean any document or other tangible thing or any electronically stored information or oral testimony that contains or reveals what a party or non-party considers to be its trade secret, business, confidential or proprietary information and that the producing party designates pursuant to this Order. Protected Information may include documents produced in the course of discovery, answers to interrogatories, answers to requests for admission, and deposition testimony and deposition exhibits that are so designated. In designating information as "Protected Information," a party or non-party ("designating party") shall designate only its trade secrets, information that it has maintained in confidence or information in which it has a proprietary interest. Each party shall act in good faith in designating information as "Protected Information."
- 2. This Protective Order establishes two categories of Protected Information. Information in the higher category is referred to as "Highly Confidential Information Attorneys' Eyes Only."

 Information in the lower category is referred to as "Confidential Information."
 - 3. The "Highly Confidential Attorneys' Eyes Only" designation may be used by a

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and programs; and may not be used for technical information relating to, referring to or concerning Sandoz's Abbreviated New Drug Application ("ANDA") No. 202575, or Roche's New Drug Application ("NDA") No. 021304 or the products that are the subject of such NDA. This designation shall be made in good faith. Protected Information that is designated as "Highly Confidential – Attorneys' Eyes Only" may be disclosed only to individuals identified in paragraphs 4(a) - 4(e). 4. The term "Qualified Person" shall mean:

designating party only for commercially-sensitive information (e.g., about business plans and objectives,

marketing, sales, revenues, profits and forecasts), products in development, and future plans, strategies

- The Court and its official personnel; a.
- Roche's outside counsel of record in this action and their law firms' active b. members, attorneys, paralegals and office staff working on this case ("Roche's Outside Counsel");
- c. Sandoz's outside counsel of record in this action and their law firms' active members, attorneys, paralegals and office staff working on this case ("Sandoz's Outside Counsel");
- d. Court reporters, stenographers, videographers, interpreters, translators, third-party photocopy, data or imaging services contractors, third-party contractors producing graphic or visual aids, jury consultants and other vendors and their respective assistants retained for the purpose of providing litigation support services to Outside Counsel;
- e. Any independent expert or consultant who is retained by Roche's Outside Counsel or Sandoz's Outside Counsel for the purpose of assisting in this action;
- f. Two in-house attorneys for Roche, provided that such in-house attorneys are identified in writing to counsel for Sandoz at least five business days prior to the disclosure of any Protected Information to such in-house attorneys and further provided that such in-house attorneys do not engage and will not engage for at least three years from the termination of this litigation, formally or informally, in any patent prosecution relating to valganciclovir, nor participate whatsoever in any communications relating to valganciclovir with the Food and Drug Administration, including in connection with a Citizen's Petition, except as may be required in order to comply with any law, regulation, or court or administrative order, e.g. such in-house attorneys may submit patent information (including on Form 3542) in connection with Roche's NDA for Valcyte® and supplements or

amendments thereto. For the avoidance of doubt, it is agreed and understood that subordinates of the identified in-house attorneys may engage in patent prosecution relating to valganciclovir so long as the identified in-house attorneys do not personally participate in such prosecution, and provided that such identified in-house attorneys do not communicate any confidential information learned during this litigation to such subordinates for any purpose relating to such prosecution and do not communicate with such subordinates regarding this case or patent prosecution relating to valganciclovir;

- g. Two in-house attorneys for Sandoz, provided that such in-house attorneys are identified in writing to counsel for Roche at least five business days prior to the disclosure of any Protected Information to such in-house attorneys and further provided that such in-house attorneys do not engage and will not engage for at least three years from the termination of this litigation, formally or informally, in any patent prosecution relating to valganciclovir, nor participate whatsoever in any communications relating to valganciclovir with the Food and Drug Administration, including in connection with a Citizen's Petition, except as may be required in order to comply with any law, regulation, or court or administrative order. For the avoidance of doubt, it is agreed and understood that subordinates of the identified in-house attorneys may engage in patent prosecution relating to valganciclovir so long as the identified in-house attorneys do not personally participate in such prosecution, and provided that such identified in-house attorneys do not communicate any confidential information learned during this litigation to such subordinates for any purpose relating to such prosecution and do not communicate with such subordinates regarding this case or patent prosecution relating to valganciclovir; and
- h. Any other person who is designated as a "Qualified Person" by order of the Court or by written agreement of the parties.

USE OF PROTECTED INFORMATION

5. Protected Information shall be used solely for the purpose of this action. Specifically, Protected Information shall not be used or disclosed by a Qualified Person for any purposes whatsoever other than preparing for and conducting the litigation in which the information or documents were disclosed, including appeals. For the sake of clarity, a receiving party shall not disclose Protected Information to the Food and Drug Administration or the Patent and Trademark Office for any reason

| whatsoever except as may be required in order to comply with any law, regulation, or court or |
|--|
| administrative order. For the avoidance of doubt, a receiving party shall not disclose or refer to Protected |
| Information in Citizens' Petitions submitted to the Food and Drug Administration. |

- 6. Nothing in this Protective Order shall prevent any person, including a Qualified Person, from making use of any information that is designated as Protected Information if such information:
- a. Was lawfully in his or her possession prior to receipt under the provisions of this Protective Order or the Confidentiality Agreement;
 - b. Was or becomes available to the public through no fault of the Qualified Person;
- c. Was or is obtained from a source not under an obligation of secrecy to the designating party;
- d. Is exempted from the operation of this Protective Order by written consent of the designating party; or
 - e. Is exempted from the operation of this Protective Order by order of this Court.

DISCLOSURE OF PROTECTED INFORMATION

- 7. Protected Information shall not be made available to anyone other than a person to whom disclosure is permitted under paragraph 4, above, or the designating party, except as otherwise provided in this Protective Order.
- 8. A document that contains or reveals Protected Information may be shown to any witness testifying under oath if the witness is indicated in such document to be its originator or author or recipient of a copy.
- 9. Protected Information may be disclosed to a witness testifying under oath if the witness is an officer, director or employee of the designating party.
 - 10. Protected Information may be disclosed to a witness testifying under oath if:
- a. The witness was formerly an officer, director or employee of the designating party; and
- b. The Protected Information was in existence during the period of his or her service or employment; and
 - c. Prior to showing Protected Information to such witness, a foundation is established

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that the witness was involved in the project to which the Protected Information relates or previously had access to or knowledge of the Protected Information so that it is reasonable to conclude that the witness had access to the Protected Information during the course of his or her service or employment.

- 11. Nothing in this Protective Order shall prevent disclosure of Protected Information if the designating party consents to such disclosure or if the Court, after notice to all parties, orders such disclosure.
 - 12. Regarding disclosure of Protected Information to Qualified Persons:
- Counsel desiring to disclose Protected Information to an independent expert or consultant according to subparagraph 4(e) shall first obtain a signed declaration in the form shown in attached Exhibit A from that person. At least ten (10) days in advance of the first proposed disclosure of any Protected Information to that person, counsel shall serve on all parties by facsimile or electronic mail that person's signed declaration and curriculum vitae or resume. A producing party may object to such disclosure on the grounds that the identified expert or consultant: (i) regularly works for or consults with the producing party (or has worked for or consulted with the producing party within the previous three years) concerning valganciclovir and the expert or consultant had access to confidential or proprietary information concerning valganciclovir from the producing party; or (ii) regularly works for or consults with a known business competitor of the producing party having competing products in the same market as valganciclovir, in a capacity other than providing litigation support or testimony, concerning valganciclovir. For the avoidance of doubt, a producing party does not hereby waive the right to enforce any contractual rights (including contractual rights of confidentiality) that may independently be owed to the producing party by an identified expert or consultant. Any objection pursuant to this provision must be made in writing and served upon each other party within ten (10) days after receiving the signed declaration. Failure to timely object shall operate as a waiver of the objection and the witness or consultant shall thereafter be qualified to receive Protected Information. In the event the producing party makes a timely objection, it must also seek relief from the Court within ten (10) days from the date the producing party made its written objection (or within such time as agreed between the Parties); otherwise such objection shall be deemed to be withdrawn and the witness or consultant shall thereafter be qualified to receive Protected Information. The objecting party shall have the burden of proving that

disclosure should not be made. If a designating party timely objects to the proposed disclosure and such objection is not withdrawn, the objecting party's Protected Information shall not be disclosed to the identified expert or consultant until the objection has been resolved by the Court or by the parties.

b. Counsel desiring to disclose Protected Information to a person according to paragraphs 4(f) or 4(g) shall first obtain a signed declaration in the form shown in attached **Exhibit A** from that person.

<u>IDENTIFICATION AND MARKING OF PROTECTED INFORMATION</u>

- 13. Any document or other tangible thing that contains or reveals Protected Information shall be labeled with the legend "CONFIDENTIAL INFORMATION SUBJECT TO PROTECTIVE ORDER" or the legend "HIGHLY CONFIDENTIAL INFORMATION ATTORNEYS' EYES ONLY SUBJECT TO PROTECTIVE ORDER." Such designations shall be made in good faith. For a document, such marking shall appear on each page of the document that contains Protected Information, provided that the requirement to mark each page shall not apply where copies are produced of documents that were produced in prior litigation and were marked in some other manner to indicate their confidential status. Any Protected Information not reduced to documentary or physical form or which cannot be conveniently labeled shall be so designated by the designating party by serving written notice on all parties. Any document or other tangible thing so labeled and the information it contains or reveals shall be treated in accordance with the provisions of this Protective Order.
- 14. When a party initially produces documents for inspection, no marking need be made by the producing party in advance of the inspection. There will be no waiver of confidentiality by the inspection of Protected Information before it is copied and marked confidential pursuant to the procedure of paragraph 13. For purposes of the inspection, all documents shall be treated as Highly Confidential Information Attorneys' Eyes Only. After the inspecting party selects documents for production, the producing party shall appropriately mark the copies of the selected documents before they are provided to the receiving party.
- 15. Information disclosed at the deposition of a party or one of its present or former officers, directors, employees or agents may be designated as Protected Information by that party either (a) on the record at the deposition or (b) by serving a written notification on each other party within twenty-five

(25) days of receipt of the transcript by counsel for the designating party. Such written notification shall identify the specific pages and lines of the transcript that contain Confidential Information or Highly Confidential Information – Attorneys' Eyes Only. A copy of such written notification shall be attached to the face of the transcript and each copy of the transcript in the possession, custody or control of any Qualified Person. All information disclosed during a deposition shall be treated as Highly Confidential Information – Attorneys' Eyes Only until at least thirty (30) days after a transcript of the deposition is received by counsel for each of the parties. A deponent may review the transcript of his or her deposition at any time.

- 16. Only Qualified Persons and the deponent shall be allowed to attend any portion of a deposition in which Protected Information is used or elicited from the deponent.
- 17. Deposition transcripts containing Protected Information shall be prominently marked on the front page with a statement that provides "THIS DEPOSITION TRANSCRIPT CONTAINS PROTECTED INFORMATION THAT IS SUBJECT TO PROTECTIVE ORDER."

DRAFTS OF EXPERT REPORTS

18. The parties agree that no party or independent expert witness or consultant is required to maintain or produce drafts of expert reports, or communications with Outside Counsel relating to the captioned matter, or notes made or taken during preparation of expert reports. Facts and data generated or reviewed by an expert will become discoverable if and when such expert is designated as a testifying expert witness, and the parties and testifying experts shall fully comply with all other disclosure requirements of Rule 26(a)(2) of the Federal Rules of Civil Procedure.

INADVERTENT FAILURE TO DESIGNATE

19. The inadvertent failure by a party to designate specific documents or materials as containing Protected Information shall not be deemed a waiver in whole or in part of a claim of confidentiality as to such documents or materials. Upon notice to each party of such failure to designate, each party shall cooperate to restore the confidentiality of the inadvertently disclosed information.

CHALLENGES TO PROTECTED INFORMATION DESIGNATION

20. If any party disputes or challenges the designation of any information as Protected Information, such information shall nevertheless be treated as Protected Information in accordance with

the provisions of this Protective Order until such designation is removed by order of the Court or by written consent of the designating party.

- 21. A party shall not be obligated to challenge the propriety of a Protected Information designation at the time made, and a failure to do so shall not preclude a subsequent challenge thereto. In the event that a party disagrees at any time with a Protected Information designation made by another party, a good faith attempt to resolve the dispute on an informal basis shall be made by the parties. In the event the dispute cannot be resolved informally, the following procedure shall be used:
- a. The party seeking the removal of the designation of Protected Information shall give Outside Counsel for the designating party notice thereof, in writing, specifying the information, documents or things for which such removal is sought and the reasons for the request. The designating party shall have fourteen (14) days after receiving that notification within which to object to the removal of protection afforded by this Order. Any such objection shall be made in writing. Failure to object within the requisite time limit is deemed a waiver of any claim to protection for that specific information, document or thing under this Protective Order.
- b. If the designating party objects in a timely fashion, then the party seeking the removal of protection for the designated Protected Information shall file and serve a motion with the Court; the designated material shall continue to be treated as Protected Information until the issue is resolved by Order of this Court or by agreement of the parties in dispute over the designation of Protected Information.
- c. On any motion arising out of the designation of any material as Protected Information under this Protective Order, the burden of justifying the designation shall lie with the designating party.

INADVERTENT PRODUCTION OF PRIVILEGED INFORMATION

- 22. Inadvertent production of materials or documents subject to the attorney-client privilege, work-product immunity or any other applicable privilege or immunity shall not constitute a waiver of such privilege(s), provided that the provisions set forth herein are followed. Inadvertent production of materials or documents shall be handled as follows, without prejudice to the right of any party to apply to the Court for further protection or disclosure relating to discovery:
 - a. Upon discovering that information produced in discovery should have been

withheld on the basis of privilege or immunity, the producing party shall immediately notify all other parties, identifying the documents or information in question and the privilege or immunity invoked. Within five (5) business days of sending such notice, the designating party shall provide to the other parties a privilege log or other description that lists the privilege information. Upon receiving such privilege log notice or other description that lists the privilege information, the receiving party shall within five (5) business days, return to the producing party the materials or documents and all copies thereof or certify to the producing party that all copies thereof have been destroyed, except that if the receiving party intends to challenge the designation of privilege or immunity, the receiving party may retain a copy until such challenge has been resolved. After receiving the notice, the receiving party shall not review, copy or otherwise disseminate the documents or materials, or disclose their substance, except insofar as may be necessary to challenge the designation of privilege or immunity.

- b. If the receiving party believes it has a good-faith basis for challenging the privilege claim, Outside Counsel for the receiving party shall provide to Outside Counsel for the producing party, within five (5) business days after receipt of the privilege log or other description that lists the privilege information, a written explanation of the good-faith basis for its belief that the inadvertently produced materials or documents are not privileged.
- c. Outside Counsel for the producing party shall respond in writing to the timely challenge to the privilege or immunity claim by Outside Counsel for the receiving party within five (5) business days from receipt of the challenge.
- d. In the event the parties cannot agree as to the privilege or immunity status of the inadvertently produced materials or documents, the receiving party has fourteen (14) days from receipt of the producing party's written response to the privilege challenge to seek relief from the Court compelling production of the inadvertently produced materials or documents. In the event that the challenge to a claim of privilege comes before the Court, the producing party shall have the burden of proving that the produced materials or documents are privileged and were inadvertently produced.
- 23. Notwithstanding any other provision of this Protective Order, failure by the producing party to provide notice of inadvertent production within 21 days after the receiving party has used a material or document during a deposition or as an exhibit to a pleading filed with the Court, identified

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such material or document for use at trial, or otherwise disclosed it to the Court, shall constitute a waiver of any and all applicable privileges with respect to the inadvertently produced materials or documents.

FILING OF PROTECTED INFORMATION

24. If a Receiving Party files Protected Information with the Court, it shall seek leave pursuant to Civil Local Rule 79-5 to file such material under seal, unless written permission to file such material publicly has been granted by the Designating Party or by a court order secured after appropriate notice to all interested persons. If a Receiving Party's request to file Protected Material under seal pursuant to Civil Local Rule 79-5(d) is denied by the Court, then the Receiving Party may file the Protected Material in the public record pursuant to Civil Local Rule 79-5(e) unless otherwise instructed by the Court.

DISCOVERY REQUESTS RECEIVED FROM THIRD PARTIES

25. In the event that any Protected Information in the possession, custody or control of any receiving party is sought by subpoena or other legal process, including compulsory process issued by any court, administrative, regulatory or legislative body, or any other person or tribunal purporting to have the authority to seek such information, the receiving party to whom the process or discovery request is directed shall: (1) give written notice of such process or discovery request, together with a copy thereof, to Outside Counsel for the producing party, and request an agreement to make the requested disclosure; (2) refuse to produce any Protected Information as long as permitted under law until such a time that the producing party has had a reasonable opportunity to object, which reasonable time to object shall not be less than ten (10) business days from the date of receipt of the notice under (1); and (3) in the event that the producing party objects as provided under (2) and the parties fail to reach an agreement to make the requested disclosure, the producing party may move the Court for an order that the disclosure not be made. An agreement in the form of Exhibit A must be obtained from all persons to whom disclosure is made under this section, or under such other conditions to which the producing party may agree or that the Court may order.

ADVICE TO CLIENTS

Nothing in this Protective Order shall bar or otherwise restrict an attorney herein from rendering advice to his or her client with respect to this action and, in the course thereof, referring to or

relying upon his or her examination of Protected Information. In rendering such advice and in otherwise communicating with his or her client, the attorney shall not disclose any Protected Information if such disclosure would be contrary to the provisions of this Protective Order.

MISCELLANEOUS

- 27. No party shall be responsible to another party for any use made of information that is produced and not designated as Protected Information.
- 28. Nothing in this Protective Order shall prejudice the right of any party to object to production of any information for lack of relevance, privilege or any ground other than confidentiality.
- 29. Nothing in this Protective Order shall prejudice the right of any party to seek at any time a further order modifying this Protective Order.
- 30. In the event that a new party is added, substituted or brought in, this Protective Order will be binding on and inure to the benefit of the new party, subject to the right of the new party to seek relief from or modification of this Protective Order.
- 31. The terms of this Protective Order may be applied to the documents, information and things received by a party from any person who is not a party to this litigation at the election of such person, provided that the nonparty so designates such documents, information and things.
- 32. Nothing in this Protective Order shall prejudice the right of any party to bring before the Court at any time the question of whether any greater or lesser restrictions should be placed upon the disclosure of any Protected Information. Nevertheless, no information may be withheld from discovery on the ground that the material to be disclosed requires protection greater than that afforded by this Protective Order unless the party claiming a need for greater protection moves for an order providing such special protection pursuant to Fed. R. Civ. P. 26(c).
- 33. Within ninety (90) days after the termination of this litigation, including any appeals and petitions for review, each document and each other tangible thing that contains or reveals Protected Information and any copies, abstracts, summaries, notes or other records regarding the contents of any Protected Information shall be either (a) returned to the attorney of record for the designating party or (b) destroyed with a written representation of such destruction being made to the attorney of record for the designating party. Notwithstanding the foregoing, each Outside Counsel for each party may keep one (1)

Telephone:

Facsimile:

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415-362-6666

415-236-6300

Telephone: +1 202 776 7800

Facsimile: +1 202 776 7801

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| 1 | Attornava for Digintiffs and Countains | E-mail:kbmctigue@duanemorris.com | |
|-----|--|--|--|
| 2 | Attorneys for Plaintiffs and Counterclaim Defendants | VINCENT L. CAPUANO (pro hac vice) | |
| 3 | GENENTECH, INC. and ROCHE PALO ALTO LLC | LAURA A. VOGEL (pro hac vice) 470 Atlantic Ave., Suite 500 | |
| 4 | Dated: October 17, 2011 | Boston, MA 02210 Telephone +1 857 488-4200 | |
| 5 | , | Facsimile +1 857 488-4201 E-mail vcapuano@duanemorris.com | |
| 6 | | lavogel@duanemorris.com | |
| 7 | | Attorneys for Defendant and Counterclaim Plaintiff SANDOZ INC. | |
| 8 | | Dated: October 17, 2011 | |
| 9 | | | |
| 10 | ATTESTATION | | |
| 11 | I, Joshua H. Lerner, am the ECF User whose identification and password are being used to | | |
| 12 | file this document. Pursuant to General Order 45.X.B, I hereby attest that counsel for Defendant and | | |
| 13 | Counterclaim Plaintiff Sandoz Inc. has concurred in this filing. | | |
| 14 | /s/ Joshua H. Lerner | | |
| 15 | | Joshua H. Lerner | |
| 16 | SO ORDERED this 17th day of October 2011: | | |
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| 18 | Jeffrey SWhits | | |
| 19 | Jeffrey S. Y lije United States District Court Judge | | |
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| - 1 | [PROPOSED] STIPLII ATED PROTECTI | VE ORDER / CASE NO. 3:11-CV-01925-ISW | |

1 2 3 4 **EXHIBIT A** 5 6 7 IN THE UNITED STATES DISTRICT COURT 8 9 FOR THE NORTHERN DISTRICT OF CALIFORNIA 10 SAN FRANCISCO DIVISION 11 GENENTECH, INC. and Case No. 3:11-cv-01925-JSW Related Case No. 3:11-cv-02410-JSW ROCHE PALO ALTO, LLC, 12 Plaintiffs and Counterclaim Defendants, DECLARATION AND AGREEMENT TO BE 13 **BOUND** v. Ctrm: 11, 19th Floor 14 Judge: Honorable Jeffrey S. White SANDOZ, INC. 15 Defendant and Counterclaim Plaintiff. 16 17 18 I, declare and state under penalty of perjury that: 19 My address is 1. 20 My present employer is and the address of my present 2. 21 employer is 22 My present occupation or job description is _____ 3. 23 24 4. I have received and carefully read the Stipulated Protective Order in the above-captioned 25 case, which is dated ______, 2011. I certify that I understand the terms of that Protective 26 Order, recognize that I am bound by the terms of that Order and agree to comply with those terms. 27 Further, I understand that unauthorized disclosure of any Protected Information, or its substance, may 28 [PROPOSED] STIPULATED PROTECTIVE ORDER / CASE NO. 3:11-CV-01925-JSW

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| 1 | constitute contempt of this Court and may subject me to sanctions or other remedies that may be impose | | |
|----|--|--|--|
| 2 | by the Court and to potential liability in a civil action for damages by the disclosing party. | | |
| 3 | Pursuant to 21 U.S.C. § 1746, I declare under penalty of perjury under the law of the United | | |
| 4 | States of America that the foregoing is true and correct. | | |
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